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C O N F I D E N T I A L SECTION 01 OF 02 AMMAN 000725

SIPDIS

STATE FOR NEA/ARN
STATE ALSO FOR EB/TPP/MTA/IPC - P. QUIGLEY
PASS TO USTR FOR E. SAUMS
USDOC 4110/ITA/MAC/OAC/TCC/JSTRADTMAN
USDOC 4520/ITA/MAC/OME/NWIEGLER

E.O. 12958: DECL: 01/25/2014
TAGS: ETRD KIPR PREL JO
SUBJECT: JORDAN FDA DECISION ON OSTEOPOROSIS DRUG GENERIC RAISES IPR CONCERNS

REF: AMMAN 460

Classified By: DAVID M. HALE, CDA. REASONS: 1.5 (B,D)

¶1. (C) SUMMARY: Jordan appears on a collision course with Merck Sharp and Dohme over MSD's osteoporosis drug, FOSAMAX OW, which a Jordanian drug firm called JOSWE is marketing as a generic after receiving permission last September from the Jordan Food and Drug Administration (JFDA). After informal discussions with the JFDA failed last fall, and an MSD court case was dismissed on a technicality in January, MSD plans to go back to court. According to PhRMA's regional rep, the association could file a recommendation to return Jordan to the Special 301 Watch List. END SUMMARY.

Court Rules Against MSD

¶2. (C) The gist of MSD's complaint revolves around clinical data protection and the difference between the FOSAMAX (aldenomax) daily and weekly formulations. Smaller, daily doses of FOSAMAX are already being sold as generics in Jordan, the five-year registration period having expired. When MSD registered the once-weekly (OW) dose in June, 2001, it expected a five-year protection of the registration, which includes protection of the proprietary clinical data on which the application was based. However, the JFDA and its internal committees appeared to have allowed the OW-formulation clinical data to be used prematurely by generic manufacturer Jordan Sweden Medical and Sterilization (JOSWE). As MSD said in a letter to the Ambassador, the JFDA was misinterpreting the application of data protection (afforded by both Jordanian law and WTO obligations) by maintaining that Jordan's FDA law only covered new chemical entities with novel active ingredients, a decision MSD labeled as having "severe negative implications" for the innovative pharmaceutical industry. (NOTE: The bilateral Free Trade Agreement (FTA), Article 4, para 22 not only states Jordan's affirmative obligation to protect such clinical data from unfair commercial use, but also the simple, direct responsibility to "protect such information against disclosure." END NOTE.)

¶3. (C) MSD initially tried to address this informally with the JFDA and senior Jordanian trade officials. They also approached JOSWE to see if a mutually agreeable solution is possible. When these steps failed, MSD filed a complaint in Jordan courts in late 2003. According to Ramsey Morad, MSD Jordan Country Director, the court ruled January 14 that the MSD complaint did not specify the offending party or the substance of the case (a JFDA Technical Committee had approved JOSWE's "LF-1" form request to register the generic, but these key details were missing) and therefore threw the case out. MSD plans to go back to court using its London-based regional office (MSD/UK) as a new plaintiff and correcting the technical deficiencies. Morad said that JOSWE does not know that MSD is "going after them again" and that MSD will not quit in defending its right to five years of exclusive marketing for the OW formulation. MSD is asking that the JOSWE product be de-registered. Morad states that MSD does not know what the JFDA's exact ruling on the JOSWE application was. The court case, if it had been allowed to proceed, would have helped ascertain the facts through discovery.

¶4. (U) NOTE: Most pharmaceuticals patented outside Jordan are placed for registration with the JFDA, which affords five years of exclusive marketing protection. Although a patent offers 20 years of protection in Jordan and/or the patent protection of the country of origin, representatives for major pharmaceutical companies say that the economics of the 2-3 year application process in this market justify the five-year protection, which would generally match the remaining exclusivity of the same drug in the U.S. END NOTE.

Embassy Advocates for MSD

¶5. (C) In a letter and subsequent conversations with Deputy PM and Minister of Industry and Trade Halaiqa, the Ambassador has advocated that the case should have been resolved through regulatory relief. Instead, the GOJ unnecessarily allowed it to escalate into a costly court case that will lead potential investors to look twice at Jordan. We have repeatedly expressed the opinion that the matter can still be resolved by GOJ action. PhRMA's regional rep, Samir Mansour, said January 20 that PhRMA may pursue Special 301 action against Jordan if this case is not resolved in MSD's favor. He also said that this is part of what he sees as a pattern of weak enforcement of IPR laws.

Royal Interest

¶6. (C) Morad told Econoff that King Abdullah used the occasion of a WEF business luncheon in Davos last week to speak directly to an MSD rep. The King reportedly told Jeff Keprecos, MSD External Affairs Director for Europe, the Middle East and Africa, that he had heard about the Merck case. Morad said that Keprecos interpreted the King's questions about the case as being generally supportive. The King reportedly said that he wanted to create a good regulatory environment in Jordan. At the King's request, MSD is sending a file on the case to the royal court this week.

Comment

¶7. (C) This case illustrates the level of complexity of IPR cases in Jordan and the need to get the government to rise to a new level of commitment in dealing with them. DPM Halaiqa told the Ambassador (septel) that he thought the JFDA was given too wide a mandate under Jordan's FDA law. It would appear the JFDA is using that mandate to continue a trend of leaning toward support of Jordan's generics manufacturers where possible, and even where the facts would not appear to support their position.

¶8. (C) At the same time, at a business luncheon at WEF on January 24, Mazen Darwazeh, chairman of industry leader Hikma Pharmaceuticals, boasted of Jordan's position in the region with a mature group of companies accessing a market of 300 million, capable of conducting clinical trials. He also reportedly boasted of Jordan's adherence to international IPR agreements. Jordan's adherence to the highest IPR standards is critical to the aspirations of the industry, which has prospered since Jordan joined the WTO. Several PhRMA firms have entered into joint agreements with local companies. This and other progress will be jeopardized if Jordan doesn't get its legal and regulatory house in order. END COMMENT.
HALE